

# United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/813,080	03/31/2004	Wallace Lynn Smith	MacBride86067-001	5650		
7590 08/18/2005		~	EXAM	EXAMINER		
William L. MacBride, Jr.			ASTORINO, MICHAEL C			
33 South Last C Helena, MT 5			ART UNIT	PAPER NUMBER		
<b>, -</b>			3736			

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	1				SP		
		Applicat	tion No.	Applicant(s)			
Office Action Summary		10/813,6	080	SMITH, WALLACE	LYNN		
		Examine	er	Art Unit			
		Michael	C. Astorino	3736			
Period fo	The MAILING DATE of this commu or Reply	nication appears on th	ne cover sheet with the	correspondence add	lress		
THE - Exte after - If the - If NC - Failt Any	MAILING DATE OF THIS COMMUN MAILING DATE OF THIS COMMUN ensions of time may be available under the provision of SIX (6) MONTHS from the mailing date of this come period for reply specified above is less than thirty (c) period for reply is specified above, the maximum sure to reply within the set or extended period for reply received by the Office later than three months leed patent term adjustment. See 37 CFR 1.704(b).	NICATION.  ns of 37 CFR 1.136(a). In no e  nmunication.  (30) days, a reply within the sta  statutory period will apply and  ly will, by statute, cause the ap	event, however, may a reply be to atutory minimum of thirty (30) da will expire SIX (6) MONTHS fror oplication to become ABANDON	imely filed  ys will be considered timely.  the mailing date of this cor  ED (35 U.S.C. § 133).	nmunication.		
Status							
1)  🛛	Responsive to communication(s) fil	led on 3/3/2004.					
· · · · ·	☐ This action is <b>FINAL</b> . 2b)⊠ This action is non-final.						
3)□	<i>,</i> —						
Disposit	ion of Claims	·					
5)□ 6)⊠ 7)□	Claim(s) <u>1 and 2</u> is/are pending in the 4a) Of the above claim(s) is/are allowed.  Claim(s) <u>1-2</u> is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restrict the subject th	are withdrawn from c					
Applicat	ion Papers						
9)[	The specification is objected to by the	he Examiner.					
10)[	The drawing(s) filed on is/are	e: a) accepted or b	o)  objected to by the	Examiner.			
	Applicant may not request that any objection	ection to the drawing(s)	be held in abeyance. Se	ee 37 CFR 1.85(a).			
11)	Replacement drawing sheet(s) includin The oath or declaration is objected	•	<del>-</del> ···	-	` '		
Priority (	under 35 U.S.C. § 119						
а)	Acknowledgment is made of a claim  All b) Some * c) None of:  1. Certified copies of the priority  2. Certified copies of the priority  3. Copies of the certified copies application from the Internations  See the attached detailed Office actions	y documents have be y documents have be s of the priority docum onal Bureau (PCT Ru	en received. en received in Applicat nents have been receiv ule 17.2(a)).	tion No ved in this National S	Stage		
Attachmen	ut(s)						
	ce of References Cited (PTO-892)		4) Interview Summary				
3) 🛛 Infor	ce of Draftsperson's Patent Drawing Review ( mation Disclosure Statement(s) (PTO-1449 o er No(s)/Mail Date <u>3/3/2004</u>		Paper No(s)/Mail D 5) Notice of Informal 6 6) Other:		152)		

Application/Control Number: 10/813,080

Art Unit: 3736

#### **DETAILED ACTION**

## Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter since the claimed invention fails to produce a useful, tangible, and concrete result.

Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter that fails to produce a useful, tangible, and concrete result. The claimed invention does not produce a "tangible" result in the sense that it merely manipulates abstract ideas without producing a physical transformation or conversion of the subject matter expressed in the claim to produce a change of character or condition in some physical object.

See In re Warmerdam, 31 USPQ2d 1754 (Fed. Cir. 1994); In re Schrader, 30 USPQ2d 1445 (Fed. Cir. 1994). A method of diagnosing a probability of pain relief through medical treatment in a patient and the steps claimed is no more than a manipulation of an abstract idea.

In this case, the method comprises, according to claim 1, steps 1(a)-(q). The steps include administering a perceptual test, receiving responses, providing and applying scoring templates, etcetera, until values are summed to produce a pain index score. These steps are not a tangible entities having substance. As such, claim 1 recites the manipulation of abstract ideas, lacks practical utility, and fails to achieve a useful, concrete, and tangible result.

Secondly, the method of diagnosing a probability of pain relief through medical treatment in a patient does not produce concrete, substantially repeatable results. Otherwise stated, it is extremely unlikely that two separate people with the same actual probability of pain relief through medical treatment will answer the same questions the same way to produce the same outcome. Or, the same patient will respond to the same questions with the same answers to produce the same results. In either case, the method is not substantially repeatable.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The lacking specific and substantial asserted utility is directed to the lack of substantially repeatability.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the examiner if the applicant is claiming alternative limitations.

Art Unit: 3736

Specifically as to claim limitations 1(c), 1(d), they fail to provide for alternative limitations. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. In this case the applicant appears to claiming an alternative expression, yet logically no alternative can be completed. Otherwise stated, in claim 1(c) the applicant claims "providing at least *three* scoring templates... selected form the group of validity factors... defensiveness, predictiveness, and carelessness." The limitation drafted in this manner creates only one possibility exists-no alternatives exist. The one possibility is defensiveness, predictiveness, and carelessness being the three scoring templates. In regards to the claim limitation 1(d), the same error exists, only with <u>six</u> instead of three factors.

Additionally, the applicant should review claim limitations 1(g), 1(i), and 1(k) to be certain the applicant's intentions are accurately represented. See MPEP 2173.05(h)

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamlin et al. "Predicting Surgical Outcome for Pain Relief and Return to Work." (cited by applicant).

In regards to claims 1-2, Hamlin et al. teaches the use of the Paindex analysis yielding a Pain Index Score and a Probability Equation score. The Paindex test is taught as having three validity scales and ten clinical scales. Additionally, the Pain Index score is calculated using the

Page 5

Art Unit: 3736

10 scales of the MMPI clinical profiles. (See entire document, particularly the subheading Patients and Methods.)

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Michael C Astorino** whose telephone number is **571-272-4723**. The examiner can normally be reached on Monday-Friday, 8:30AM to 3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Astorino August 12, 2005